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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/889,355	07/08/1997	HEIDRUN ENGLER	16930-000811	3379

7590

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EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/889,355

Applicant(s)

ENGLER ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41 and 54 is/are pending in the application.
- 4a) Of the above claim(s) 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10-20-03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments filed 10-20-03 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-40 and 42-53 have been canceled. Claim 54 has been added. Claims 41 and 54 remain pending in the instant application. The effective filing date of the claimed invention remains July 8, 1997.

Election/Restrictions

Newly submitted claim 54 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: it is not readily apparent that the structure of 3'-N-gluconamidopropyl-3"-N-cholamidopropyl-N-cholamide as newly claimed is related to the compound originally claimed. The compound of Claim 54 would require a different search not previously required.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 54 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 41 is under consideration in the instant office action.

Claim Rejections - 35 USC § 112

1. Claims 41 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record.

Claim 41 is drawn to a compound wherein X1 and X2 are both cholic acid groups and X3 is a pentose monosaccharide group. The specification teaches isolating Impurities I, II and III from BigCHAP; however, the specification does not describe their structure. Since the time of filing, the structure of Impurities I, II and III have been determined (see Fig. 22, 23 and 24 in US Application 09/112,074, now US Patent 6,392,069).

Impurity I does not correlate to the compound of claim 41 because Impurity I does not have the same tertiary nitrogen as the compound in claim 41.

Impurity III does not correlate to the compound of claim 41 because X1 is a saccharide group in Impurity III while X1 is a cholic acid group in the compound claimed.

Since the time of filing Impurity II has been described as a compound having both X1 and X2 as cholic acid groups and X3 as a pentose monosaccharide. The specification as originally filed did not adequately describe Impurity II as a compound having both X1 and X2 as cholic acid groups and X3 as a pentose monosaccharide. Example 12 (pg 31, lines 15-19) illustrates the procedure for making a compound but does not describe the structure of the compound; nor is it readily apparent that Example 12 is synthesizing Impurity II. Page 5, lines 2-10, does not teach both X1 and X2 were cholic acid and X3 was a pentose monosaccharide. Page 6, lines 31-32, merely states that a saccharide group found in a compound of Formula I (as originally filed wherein X1 and X2 had broader scopes) may be a pentose monosaccharide and does not teach or suggest that X1 and X2 are both cholic acid while X3 is a pentose monosaccharide. The structure of Impurity II is not readily apparent from the specification as originally filed because the specific combination of elements in X1, X2 or X3 could not have been guessed based on the broad original description of Formula I and the broad scope of

possibilities for X1, X2 and X3. Without such guidance, the specification as originally filed did not adequately describe the structure of the compound of claim 41, specifically that the compound had the properties of Impurity II.

While Impurity II is a species within the genus of compounds contemplated as "Formula I" in the specification as originally (see original claim 1), the specific structure of Impurity II and now claimed was not disclosed or readily apparent from the specification. Nor did the specification as originally filed link the ability to increase transfection of nucleic acids into cells found in Impurity II with a compound having a structure as now claimed. An adequate written description of Impurity II requires more than a mere description of the genus of the compound and a statement that Impurity II was isolated and part of the invention. What is required is a description of the structure of Impurity II itself. It is not sufficient to state Impurity II is one of a host of possible combinations of elements because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of the specific structure of Impurity II. Thus, claiming a compound without describing the specific structure of the compound is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

Impurity II has a cholic acid group attached at X1 and X2 such that the terminal CO₂H of cholic acid is removed; however, the manner in which cholic acid is attached at X1 and X2 was not disclosed in the specification as originally filed. It is not readily apparent from the description of Impurity II that X1 and X2 were cholic acid with a deletion of the terminal CO₂H. Applicants state a person of skill in the art would have understood Example 12 described a cholic acid group as being a cholic acid without a terminal CO₂H. Applicants' argument is not persuasive. It would not have been readily

apparent to one of skill in the art what structure would result from the method in Example 12, specifically how cholic acid would attach at X1 and X2 or the structure of cholic acid once it reacts with isobutylchloroformate in the presence of triethylamine. Nor does Example 12 teach Impurity II is the product being synthesized. It would not have been readily apparent to one of skill at the time of filing that the process described in Example 12 results in Impurity II. Example 12 does not describe 3-aminopropyl-3'-N-gluconamidopropyl-amine (the product being synthesized) as Impurity II. The specification does not describe Impurity II (isolated in Example 11, pg 28), as 3-aminopropyl-3'-N-gluconamidopropyl-amine. It would not have been readily apparent to one of skill in the art that the method in Example 12 made Impurity II or was specific to making only Impurity II. It would not have been readily apparent to one of skill that reacting cholic acid with isobutylchloroformate in the presence of triethylamine described in Example 12 would result in cholic acid without the terminal CO₂H. The at the time of filing did not define a "cholic acid group" as being cholic acid without the terminal CO₂H. Therefore, the structure of Impurity II being that of claim 41 was not readily apparent to one of skill in the art at the time of filing based on the teachings in the specification as originally filed.

2. Claim 41 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

The claim is drawn to a compound having a particular structure wherein X1 and X2 are both cholic acid groups and X3 is a pentose monosaccharide group. The specification teaches isolating Impurities I, II and III from BigCHAP; however, the

specification does not describe their structure. Since the time of filing, the structure of Impurities I, II and III have been determined (see Fig. 22, 23 and 24 in US Application 09/112,074, now US Patent 6,392,069). BigCHAP and Impurity I do not correlate to the compound of claim 41 because BigCHAP and Impurity I do not have the same tertiary nitrogen as the compound in claim 41. Impurity III does not correlate to the compound of claim 41 because X1 is a saccharide group in Impurity III while X1 is a cholic acid group in the compound claimed.

Since the time of filing Impurity II was described as a compound having both X1 and X2 as cholic acid groups and X3 as a pentose monosaccharide. The specification as originally filed did not distinguish the structure of Impurities I, II and III, so that one of skill would have known Impurity II had X1 and X2 as cholic acid groups (and not deoxycholic acid group). Nor did the specification teach X3 in Impurity II was a pentose monosaccharide group. Therefore, the structure of Impurity II is not readily apparent from the specification as originally filed because the specific combination of elements in X1, X2 or X3 could not have been guessed. Thus, it would have required one of skill undue experimentation to determine how to make or use the compound claimed as Impurity II. Furthermore, Impurity II has a cholic acid group attached at X1 and X2 such that the terminal CO_2H of cholic acid is removed; however, the manner in which cholic acid is attached at X1 and X2 is not disclosed in the specification. It is not readily apparent from the description of Impurity II that X1 and X2 were cholic acid with a deletion of the terminal CO_2H . Therefore, the structure of Impurity II is not readily apparent from the specification as originally filed because it could not have been guessed that the cholic acid group was attached such that the terminal CO_2H was deleted.

Applicants' arguments for enablement are the same as those for written description, which are addressed above in the written description rejection.

3. Claim 41 remains rejected as being indefinite because the structures encompassed by the claims are unclear for reasons of record.

The claim requires a compound having Formula I, wherein X1 and X2 are both cholic acid groups. The specification (Ex. 11) states three impurities (I, II and III) were isolated from BC BigCHAP, but does not teach the structure of the impurities or how cholic acid is attached to Formula I. The structure of Impurity II has three carbons between the carboxyl group and the pentose ring instead of four in the cholic acid (i.e. Impurity II require X1 and X2 are both a cholic acid group wherein the cholic acid group is cholic acid with a deletion of the terminal CO₂H). Addition of cholic acid to Formula I may result in i) four carbons between the carboxyl group and the pentose ring of the cholic, ii) removal of the carboxyl group, iii) or attachment at one of the hydroxyl groups. Therefore, it is unclear whether applicants intend the claim to encompass any means of attaching cholic acid to Formula I at X1 and X2 or if the claim is limited to removal of the carboxyl group of cholic acid.

Applicants' arguments for 112/2nd are the same as those for written description and enablement, which are addressed above in the written description rejection.

Conclusion

No claim is allowed.

Art Unit: 1632

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120. The Examiner's number will be changed on January 12th, 2004 to 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson

A handwritten signature in black ink, consisting of a series of vertical, wavy lines followed by a horizontal stroke.

**MICHAEL WILSON
PRIMARY EXAMINER**